



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2020-0701; **FRL-10796-01-ORD**]

Integrated Science Assessment for Lead (Pb) (External Review Draft)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period for the draft document titled, “Integrated Science Assessment for Lead (External Review Draft)”. This draft document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA’s Office of Research and Development (ORD) as part of the review of the primary (health-based) and secondary (welfare-based) Lead (Pb) National Ambient Air Quality Standards (NAAQS). It represents an update of the 2013 Integrated Science Assessment (ISA) for Lead (Pb) (EPA/600/R-10/075F). The ISA, in conjunction with additional technical and policy assessments, provides the scientific foundation for EPA’s decisions on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. EPA is releasing the draft ISA for Pb to seek review by the Clean Air Scientific Advisory Committee (CASAC) and input from the public. The date and location of a public meeting for the CASAC to discuss its review of this document will be specified in a separate *Federal Register* notice (FRN). The draft ISA is not final and does not represent, and should not be construed to represent, any final Agency policy or views. When revising the document, EPA will consider any public comments submitted during the public comment period specified in this notice.

DATES: The public comment period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] and ends [INSERT DATE 60 DAYS AFTER DATE OF PUBLICAITON IN THE FEDERAL REGISTER]. Comments must be received on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The “Integrated Science Assessment for Lead (Pb) (External Review Draft)” will be available on or about March 31, 2023 via the internet on EPA’s Integrated Science Assessment Lead page at <https://www.epa.gov/isa/integrated-science-assessment-isa-lead> and in the public docket at <http://www.regulations.gov>, Docket ID No. EPA-HQ-ORD-2020-0701. You may send comments, identified by Docket ID No. EPA-HQ-ORD-2020-0701, by any of the methods discussed in the “How to Submit Technical Comments to the Docket” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; phone: 202-566-1752; facsimile: 202-566-9744; or email: ord.docket@epa.gov.

For technical information, contact Evan Coffman; phone: (919) 541-0567; facsimile: 919-541-5078; or email: Coffman.Evan@epa.gov or Meredith Lassiter; phone (919) 541-3200; facsimile: 919-541-5078; or email: Lassiter.Meredith@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act (the Act) directs the EPA Administrator to identify and list certain air pollutants that “may reasonably be anticipated to endanger public health or welfare” and “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources.” The Act further directs the Administrator to issue air quality criteria for these pollutants. The air quality criteria are to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air...” Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which the Agency has issued air quality criteria. Section 109(d)(1) requires periodic review and, if appropriate, revision

of air quality criteria and the NAAQS to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. Information on EPA's process for reviewing the air quality criteria and the NAAQS is available at <https://www.epa.gov/naaqs>.

EPA has established NAAQS for six criteria pollutants. Presently the EPA is reviewing the air quality criteria and NAAQS for Pb. As part of that review, EPA is preparing an updated ISA to reflect the latest scientific knowledge on the public health and welfare effects of Pb exposures, per section 108(a) of the Clean Air Act. When final, the ISA, in conjunction with additional technical and policy assessments, will provide the scientific foundation for EPA's decisions on the adequacy of the current Pb NAAQS and, if appropriate, on potential alternative standards. The CASAC, an independent scientific advisory committee with review and advisory functions that are mandated by section 109(d)(2) of the Clean Air Act, will provide an independent scientific review of the draft ISA.

On July 7, 2020, (85 FR 40641), EPA formally initiated its current review of the air quality criteria for the health and welfare effects of Pb, requesting the submission of recent scientific information on specified topics. Key background information on the air quality criteria for the primary (health-based) and secondary (welfare-based) NAAQS for Pb was summarized in Volume 1 of EPA's "Integrated Review Plan for the Lead National Ambient Air Quality Standards," and the general approach to developing the Pb ISA was incorporated into Volume 2 of EPA's "Integrated Review Plan for the Lead National Ambient Air Quality Standards," which was available for public comment (87 FR 13732, March 10, 2022) and was discussed by the CASAC at a publicly accessible teleconference consultation (87 FR 15985, March 21, 2022).¹

Webinar workshops were held on May 26, June 7, June 22, and June 29, 2022, for invited EPA and external scientific experts to discuss initial Pb ISA draft materials and for the public to have an opportunity to listen in to these discussions (87 FR 27147, May 6, 2022). Input received

¹Volume 3 of the IRP will describe key considerations in EPA's planning for any exposure/risk analyses. Volume 3 will also be the subject of a future consultation with the CASAC.

during these webinar workshops aided in the development of the draft ISA for Pb being released at this time.

The next step is for the CASAC to review the draft ISA and to discuss its review at a public meeting. This meeting will include an opportunity for members of the public to address comments to the CASAC for its consideration. A separate FRN will inform the public of the date and time of the CASAC meeting and of the procedures for public participation.

II. How to Submit Technical Comments to the Docket

Submit your materials identified by Docket ID No. EPA-HQ-ORD-2020-0701 by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- E-mail: ord.docket@epa.gov
- Fax: 202-566-9744. Due to COVID-19, there may be a delay in processing comments submitted by fax.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Research and Development Docket, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. The phone number is 202-566-1752.
- Hand Delivery or Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday through Friday (except Federal Holidays). If you provide materials by mail or hand delivery, please submit three copies of these materials. For attachments, provide an index, number pages consecutively with the materials, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2020-0701. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked “late,” and will only be considered if time permits.

It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at www.regulations.gov, including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit EPA’s Docket Center homepage at <https://www.epa.gov/dockets>.

Docket: Documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Wayne Cascio,
Director,
Center for Public Health and Environmental Assessment,
Office of Research and Development.